

October 10, 2002

Wendy K. Sherman  
Technical Contact  
The American Chemistry Council  
Brominated Flame Retardant Industry Panel  
1300 Wilson Boulevard  
Arlington, VA 22209

Dear Ms. Sherman:

The Office of Pollution and Toxics is transmitting EPA's comments on the robust summaries and test plan for Cyclododecane, 1,2,5,6,9,10-Hexabromo- posted on the ChemRTK HPV Challenge Program Web site on January 31, 2002. I commend The American Chemistry Council Brominated Flame Retardant Industry Panel for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that The American Chemistry Council Brominated Flame Retardant Industry Panel advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at [tsca-hotline@epa.gov](mailto:tsca-hotline@epa.gov).

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director  
Risk Assessment Division

Enclosure

cc: C. Auer  
A. Abramson  
W. Penberthy  
M. E. Weber

**EPA COMMENTS ON CHEMICAL RTK HPV CHALLENGE SUBMISSION:  
1,2,5,6,9,10-HEXABROMOCYCLODODECANE (CAS No. 3194-55-6)**

**SUMMARY OF EPA COMMENTS**

The sponsor, the American Chemistry Council's Brominated Flame Retardant Industry Panel, submitted a test plan and robust summaries to the EPA for 1,2,5,6,9,10-Hexabromocyclododecane (HBCD, CAS No. 3194-55-6) dated December 21, 2001. EPA posted the submission on the ChemRTK HPV Challenge Web site on January 31, 2002.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Data. The submitter needs to provide boiling point information to address this endpoint. The water solubility data needs to be reviewed and recalculated.
2. Environmental Fate. The submitter needs to provide robust summaries for photodegradation/atmospheric oxidation and stability in water.
3. Health Effects. The submitter needs to provide additional information on reproductive organs evaluation from the repeated-dose toxicity studies.
4. Ecological Effects. The data are adequate for the purposes of the HPV Challenge Program.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

**EPA COMMENTS ON THE 1,2,5,6,9,10-HEXABROMOCYCLODODECANE CHALLENGE SUBMISSION**

**Test Plan**

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility).

Data are adequate for melting point, vapor pressure, partition coefficient (log Kow) and water solubility for the purposes of the HPV Challenge Program.

*Boiling Point.* No boiling point data were provided for this compound. It is likely that HBCD boils or decomposes above 300 °C; however, the submitter needs to provide supporting information in a robust summary in order to address this endpoint.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

*Photodegradation and atmospheric oxidation.* Although the photodegradation information and atmospheric oxidation data are discussed in the test plan, the submitter needs to provide the information in a robust summary.

*Stability in water.* Although a discussion occurs in the test plan, the submitter needs to provide the information in a robust summary.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

The data are adequate for acute toxicity, repeated-dose toxicity, genetic toxicity, and developmental toxicity for the purposes of the HPV Challenge Program. EPA reserves judgement on the adequacy of the data on reproductive effects pending the review of additional data.

*Acute Toxicity.* All submitted studies were deficient. However, from the weight of the evidence, EPA concludes that this endpoint has been addressed for the purposes of the HPV Challenge Program.

*Repeated-Dose Toxicity.* The submitted data adequately address this endpoint. However, it should be noted that an adequacy determination by EPA does not imply acceptance of study conclusions; such as, the submitter's conclusion that the effects on the liver and thyroid should be discarded when deriving NOAELs.

*Reproductive Toxicity.* EPA agrees that an adequate evaluation of the reproductive organs and available adequate developmental toxicity study may address this endpoint for the purposes of the HPV Challenge Program. However, the submitted information on the reproductive organs evaluation is not sufficient. The submitter needs to provide additional data on organ weights (incidence/dose-response), histopathology and other parameters observed for reproductive organs in the 90-day repeated-dose study and from the cancer bioassay to determine adequacy of this endpoint. [EPA raises this concern because increased prostate weights were noted in the 90-day repeated-dose study.]

Ecological Effects (fish, daphnia, and algal toxicity)

Adequate data are available on all endpoints for the purposes of the HPV challenge program.

**Specific Comments on the Robust Summaries**

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility).

*Water Solubility.* The submitter provides a measured water solubility of 0.0034 mg/L at 25 °C with a standard deviation of  $\pm 0.2$  mg/L that was obtained in accordance with OECD Guideline 105. This standard deviation does not agree with the measured value. The sponsor needs to address the discrepancy.

Health Effects

*Repeated-Dose Toxicity.* The key study identified by the submitter lacked of information on the purity/composition of the test material. Additional information on the reproductive organs is needed.

*Developmental Toxicity.* In the key study identified by the submitter, the test article was described as a composite of the commercial products from three companies. While the isomer composition of the mixture was given, an overall purity was not stated. According to EPA files the Stump (1999) developmental study indicates 90.0 wt.% mixed HBCD isomers; the impurities were not identified and this information should be included in the robust summary.

**Followup Activity**

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.